K033529

DEC - 3 2003

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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the TIE-IN™ Trapezium.

Submitted By:	Wright Medical Technology, Inc.
Date:	November 7, 2003
Contact Person:	Katie Logerot Regulatory Affairs Associate
Proprietary Name:	TIE-IN™ Trapezium
Common Name:	Trapezium Implant
Classification Name and Reference:	21 CFR 888.3770 Prosthesis, wrist, carpal trapezium – Class II
Device Product Code and Panel Code:	21 CFR 888.3770 Prosthesis, wrist, carpal trapezium – Class II

DEVICE INFORMATION

A. INTENDED USE

Use of the TIE-IN™ Trapezium may be considered in degenerative or post-traumatic disabilities of the thumb basil joint with:

- Localized pain and palpable crepitation during circumduction movement with axial compression of involved thumb ("grind test")
- Decreased motion, decreased pinch and decreased grip strength
- X-ray evidence of arthritic changes of the trapeziometacarpal, trapezioscaphoid, trapeziotrapezoid, and trapezium second metacarpal joints, singly or in combination
- Associated unstable, stiff, or painful distal joints of thumb or swan-neck deformity

The TIE-IN™ Trapezium is for single use.

B. DEVICE DESCRIPTION

The design features of the TIE-IN™ Trapezium are summarized below:

- Manufactured from silicone elastomer, identical to the Swanson Trapezium Implant
- Offered in 3 sizes
- Sides of the implant have an hour glass shape that can be used to wrap a tendon around and stabilize the implant
- Round peg for insertion into the canal of the ulna

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use and materials of the TIE-IN™ Trapezium are identical to the Swanson Trapezium Implant. The design features of the TIE-IN™ Trapezium are substantially equivalent to the Swanson Trapezium Implant. The safety and effectiveness of the TIE-IN™ Trapezium are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2003

Ms. Katie Logerot
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K033529
Trade/Device Name: TIE-IN™ Trapezium
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: November 7, 2003
Received: November 10, 2003

Dear Ms. Logerot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT.

Indications for Use

510(k) Number (if known): K033529

Device Name: TIE-IN™ Trapezium

Indications For Use:

Use of the TIE-IN™ Trapezium may be considered in degenerative or post-traumatic disabilities of the thumb basil joint with:

- Localized pain and palpable crepitation during circumduction movement with axial compression of involved thumb ("grind test")
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The TIE-IN™ Trapezium is for single use.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milleson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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